REMARKS

Claims 1, 3, 4, 7-10, 12-19, 25-29, 33 and 59-69 are pending in this application. Claims 1, 3, 15 and 60-65 have been amended to (1) correct typgraphical and/or grammatical errors (2) incorporate subject matter from dependent claims and (3) fix claim dependencies. Claims 12-14 have been cancelled without prejudice or disclaimer of the subject matter therein. New claims 70-76 have been added and contain subject matter in the claims as originally filed. The claims are merely of varying scope. Claims 73-75 are similar in scope to claims 70-72 except that the artificial MHC Class II peptide binding sequence has been defined as a pan DR epitope peptide. Claim 76 is similar in scope to claim 1 except that the artificial MHC Class II peptide binding sequence has been defined as a pan DR epitope peptide. Support for this amendment may be found on page 36, lines 23-30 of the Specification. No new matter has been added. Applicant sumbits that the newly added claims are patentable for the reasons set forth below an in Applicant's previous responses.

1. Oath/Declaration

The Examiner has again indicated that the Applicant is required to submit a corrected oath/declaration. Applicant submitted a corrected oath/declartion on May 12, 2004 and respectfully requests that the objection be reconsidered and removed.

2. Specification

The Specification has been objected to because it does not properly refer to those applications to which it claims benefit. Applicant has amended the Specification to incorporate Applicant's claims to domestic and foreign priority. Reconsideration and removal of the objection is respectfully requested.

3. Claim Objections

Claims 1, 15 and 60 have been rejected for various informalities. Claim 1 has been amended to correct the misspelling of "MHC". Claim 15 has been amended and now depends

from claim 3. Finally, claim 60 has been amended to remove the parentheses around the SEQ ID NOs as suggested by the Examiner. Applicant believes that the foregoing amendments have obviated the objections. Reconsideration and removal thereof is respectfully requested.

4. Provisional Double Patenting Rejection under 35 U.S.C. §101

The Examiner has again indicated that claims 1, 3, 4, 7-10, 12-19, 25-29, 33 and 59-69 are provisionally rejected under 35 U.S.C. §101 as claiming the same invention as those of claims 1-18 and 20-22 of copending Application No. 10/204,362. The Examiner has also indicated that these claims are also provisionally rejected under the judicially created doctrine of double patenting over claims 1-3 and 4-21 of copending Application No. 10/223,809. Applicant respectfully asks that these rejections be held in abeyance until the Examiner actually issues a notice of allowability in the present case.

5. Claim Rejections under 35 U.S.C. §112, first paragraph

The Examiner has indicated that Applicant's prior response obviated the rejection of the claims for lack of enablement. However, the Examiner now argues that claims 1, 3-4, 7-10, 12-19, 25-29, 33 and 59-69 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner has issued two separate rejections for lack of adequate written description support. In the first rejection, claims 1 and 59 stand rejected because the limitation "an artificial MHC Class II binding peptide sequence" fails to fully disclose the structure and nature of the sequence "thus implying that the sequence is not known or must be confirmed". In the second rejection, the Examiner has rejected claims 3-4, 12-13 and 61 because the claims require three "moieties" which perform various functions/purposes but are not defined in terms of structure or sequence "thus implying that the moieties are not known or must be confirmed". To support both of these rejections, the Examiner heavily relies upon the recent court decision in University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003). Applicant traverses both of these rejections and submits that the Examiner has

misinterpreted and misapplied the holding of Rochester.

A. Rejection of Claims 1 and 59

The Examiner has argued that Applicant is not entitled to the genus of "artificial MHC Class II binding peptide sequence" because they have failed to describe the structure or the nature of the sequence. Consequently, the Examiner argues that the Applicant is not aware of and has not confirmed that any such peptides exist. Accordingly, the Examiner argues that the claims 1 and 59 fail to satisfy the written description requirement because Applicant has not described every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. (citations omitted). Applicant respectfully disagrees.

First, it is important to note each case involving the issue of written description must be decided on its own facts and that the precedential value of cases in the area of written description is extremely limited. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991). Secondly, it is important to recognize that this inquiry is conducted from the perspective of the skilled artisan. Contrary to the Examiner's opinion, Applicant submits that the skilled artisan, after reading the Specification, would recognize that the inventors had provided sufficient written description to evidence possession of the claimed genus --- artificial MHC Class II binding peptide sequences.

As the Examiner may recall, claim 1 was amended in Applicant's last response to further define what was meant by the term "foreign T helper epitope" because this term was found to be "too broad". Applicant responded by amending the claim to specify that the foreign T helper epitope referred to MHC Class II binding peptides, whether they were of natural or artificial origin. The characterization of the epitope as "artificial" does not imply that such structures do not exist. To the contrary, examples of natural and artificial foreign T helper epitopes are well-documented in the art and would be apparent to a person of ordinary skill in the art and are described in the Specification. As noted in Applicant's prior response, there are no functional or structural differences between a naturally occurring T-helper epitope and an artificial sequence (except, of course, the precise sequence). Both are peptides and both have the ability to bind

MHC Class II and stimulate T-helper lymphocytes.

Applicant submits that a person of ordinary skill in the art would recognize and appreciate that the artificial sequences are equivalents of the naturally occuring sequences recited in the claims especially in view of the discussion at pages 33-37 of the Specification. The Specification discusses both natural and artificial (i.e. non-natural) T cell epitopes which may be employed in the invention. Examples of artifical T-cell epitopes, notably the pan DR epitope peptides (the "PADRE" epitopes) are specifically cited as being useful in the present invention. (See, p. 36-37 of the Specification). Moreover, the inventors state that any artifical epitope having the requisite lack of MHC restriction would be suitable for use in the invention. Thus, Applicant submits that, at the time the application was filed, the inventors undeniably recognized that artificial T-cell epitopes could be used in the invention.

The Examiner's reliance on the Rochester decision is misplaced as the facts in Rochester are substantially different from the present case. In Rochester, the court invalidated a patent which claimed a method of treatment expressed in functional terms for lack of written description and enablement. The claim at issue was directed to "A method of selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment." The Rochester patent did not actually disclose a compound that could accomplish the result. The court presented the written description issue as "simply whether a written description of a method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process." The court found that a patent claiming a method of obtaining a biological effect in a human by administering a compound cannot satisfy the written description requirement if there is no disclosure of the identity of any such compound. From the discussion in the underlying district court opinion, it is clear that the failure to disclose even one compound that would meet the test set out in the patent for selective COX-2 inhibitors led the district court to conclude that when the Rochester application was filed, there remained too much uncertainty regarding whether any selective inhibitors could be found, and, therefore, the Rochester inventors had not yet completed the claimed invention. The district

court's finding was upheld by the Federal Circuit and the most reasonable interpretation of the Federal Circuit holding appears to be that one may not claim a method reciting a compound as a genus where practice of the invention requires use of a compound, when the applicant has not yet proven the existence of even one compound of that functionally defined genus.

The holding in Rochester is not applicable to the present situation. Unlike Rochester where the inventors did not generally or otherwise describe even a single compound to the used in the claimed method, the present inventors have discussed and provided examples of compounds which would fall within the genus of "artificial MHC Class II binding peptide sequences". The artificial MHC Class II binding peptide sequences encompassed by the present claims are not merely "as-yet-to-be-discovered" or hypothetical compounds. Nor, are they compounds whose activity has yet to be verified or confirmed. This is simply not a case where the method cannot be practiced until a compound is discovered that achieves the desired result. The present inventors have described and provided examples of artificial MHC Class II binding peptide sequences which are known and exhibit the desired functionality and are entitled to a generic claim. Applicants are not required to provide a comprehensive list of each and every member of a claimed genus. The test is whether the skilled artisan would recognize that the Applicant was in possession of the necessary common attributes or feature of the elements possessed by the members of the genus in view of the species disclosed or claimed. As discussed above, the common attributes, features or elements possessed by the claimed genus are discussed in Applicant's Specification and would be apparent to the skilled artisan. Accordingly, Applicant submits that the skilled artisan would recognize that the inventors by disclosing and exemplifying artificial MHC Class II binding peptide sequences were "in possession" of the genus. Thus, claims 1 and 59 should be found to comply with the written description requirement and reconsideration and removal of the rejection is respectfully requested.

B. Rejection of Claims 3-4, 12-13 and 61

Claims 3-4, 12-13 and 61 have also been rejected by the Examiner for lack of adequate written description support. The Examiner argues that the claims require three "moieties" which are only described in terms of their functional properties. The first moiety effects targeting of

the analogue to an antigen presenting cell or B-lymphocyte. The second moiety stimulates the immune system and the third moiety optimizes presentation of the analogue to the immune system. The Examiner concludes that these three genera are not supported by the Specification because the Specification does not sufficiently disclose the structure or nature of these sequences. Applicant respectfully traverses the rejection.

Applicant has amended claims 3-4 and has cancelled claims 12-13 and 61. Claim 3 has been amended to further define members of the "moieties". The first moiety is defined as a specific binding partner, selected from the group consisting of a hapten and a carbohydrate, for which there is a receptor on a B-lymphocyte or an antigen-presenting cell (APC). The second moiety is defined as a cytokine, heat shock protein or hormone. And, the third moiety is defined as a lipid or polyhydroxypolymer. As claim 3 is now written, the genera are not the first, second or third moieties. Rather, the genera recited in the claims are now haptens, carbohydrates, cytokines, heat shock proteins, hormones, lipids and polyhydroxypolymers. Applicant notes that the Examiner has not rejected dependent claims 62-65 which are drawn to the species for lack of written description support. Yet, the Examiner argues that the broad genus claims are not adequately supported. Applicant respectfully disagrees.

An Applicant is entitled to a genus claim if they have described or exemplified a representative number of species. The disclosure of even a single species can adequately support a genus. (See MPEP 2163). In the present case, the inventors have provided a sufficient description of a representative numbers of species in the Specification at pages 37-39 wherein they describe and provide numerous examples of specific haptens, carbohydrates, cytokines, heat shock proteins, hormones, lipids and polyhydroxypolymers that can be used to achieve the desired result. All of these classes of compounds represent well-known and well-characterized chemical compounds. This is apparent from the description of the classes of compounds in the Specification, itself. The skilled artisan could readily identify other compounds falling within each class that might also be employed for the same purpose in the invention without engaging in any undue experimentation or a trial and error process. The fact that the claims include a functional recitation of known compounds does not necessarily mean that the written description requirement is not met. (See, MPEP 2163 citing *In re Herschler*, 591 F.2d 693, 697, 200 USPQ

711, 714 (CCPA 1979) "Occasionally, a functional recitation of those known compounds in the Specification may be sufficient as that description.") An Applicant is not required to restrict their claims to the one or two species exemplified under such circumstances and is entitled to the broad genus claim.

Again, Applicant would point out that the Rochester decision is equally inapplicable and fails to support the rejection of claims 3-4, 12-13 and 61. This is not a case where the inventors have not disclosed or identified compounds that achieve the desired result. The Specification clearly demonstrates that the inventors knew which class of compounds would perform a particular function and they provided numerous examples of such compounds. Claims 62-65 are directed to the specific compounds identified by the inventors. Applicant should not limited to just those specific compounds when no undue experimentation or trail and error process would be required to identify other compounds falling within the classes of compounds encompassed by the claims.

In view of the foregoing remarks, it is evident that the inventors have described a representative number of species and that claim 3, as amended, meets the written description standards. Reconsideration and removal of the rejection is respectfully requested.

6. Rejections under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 3 and 12 under 35 U.S.C.§112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Claim 12 has been rejected for use of the term "substantially specific" while claim 3 has been rejected for the use of the phrase "substantial fraction of B-cell epitopes". Applicant has cancelled claim 12 and incorporated the subject matter contained therein into claim 3. With respect to the second rejection, Applicant submits that the metes and bounds of the phrase "substantial fraction of B-cell epitopes" would be apparent to a person of ordinary skill in the art by reference to Applicant's disclosure. From the disclosure on pages 27-31 of the Specification and, in particular, in the paragraph bridging pages 29-30, the skilled artisan would understand the meaning of the phrase to refer to those modified peptides which would exhibit a significant and specific cross-reactivity with polyclonal

antibodies raised against the native protein. As such, Applicant submits that the term is adequately defined by the Specification and would not be considered vague or indefinite by the skilled artisan. However, soley in an effort to accelerate the allowance of the claims, Applicant has removed this phrase from the scope of the claim. Applicant believes that the foregoing amendments and remarks have addressed and obviated all of the indefiniteness rejections. Reconsideration and removal of indefiniteness rejections is therefore requested.

Favorable consideration and early allowance of all the claims is earnestly solicited.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of $950.00 is attached hereto.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on: July 30, 2004
(Date of Deposit)

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Sandra B. Pulo
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July 30, 2004
(Date of Signature)

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Respectfully submitted,

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